California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Licensing Committee Report

Clarence Hiura, Chair
Ruth Conroy, Member
John Tilley, Member

Report of September 10, 2003

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy approve the proposed regulation change to CCR, title 16, sections 1719-1728, to implement the North American Pharmacist Licensure Examination (NAPLEX) and the California Multi-State Pharmacy Jurisprudence (MPJE) examination.

Discussion

SB 361 (Figueroa) is the legislative vehicle for the Board of Pharmacy sunset extension and contains statutory recommendations approved by the Joint Legislative Sunset Review Committee. Governor Davis signed SB 361, which authorizes the board to implement NAPLEX and develop the California MPJE. To do this, the board must modify its regulations as recommended by the Licensing Committee.

Implementation of NAPLEX and California MPJE

SB 361 allows an applicant who has passed the NAPLEX and the California MPJE on or after January 1, 2004, to be licensed as a pharmacist. Specifically, the bill requires the board when developing the California MPJE to include all of the following:

- examination items to demonstrate the candidate's proficiency in patient communication skills
- aspects of contemporary standards of practice for pharmacists in California including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the NAPELX

The bill also requires the board to work with the Office of Examination Resources or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

Tracy Ferrel, Ph.D., Chief, Department of Consumer Affairs, Office of Examination Resources, updated the Licensing Committee on the transition to the NAPLEX and California MPJE.

She stated that the bulk of the board's activities have been to develop a content outline for the California MPJE that encompasses areas identified in California's job analysis that are not covered by the NAPLEX, and that contain items on patient communication and California law which are specifically required by SB 361.

The board's Competency Committee completed the development of the California MPJE's content outline during an August meeting, and Dr. Ferrel discussed the new content outline. She noted that there was substantial overlap between the content outline for NAPLEX and for California's current pharmacist examination. The California MPJE will be comprised of 75 graded items and 15 pretest items (nongraded items that will not be identified as pretest items). **(Attachment A – California MPJE Content Outline)**

The Competency Committee is now developing questions for the California MPJE based on the new content outline. By December 1st, there will be a number of questions ready for administration.

An applicant for licensure in California must also apply concurrently to NABP to take NAPLEX or to have a NAPLEX score transferred to California. It will be the board's determination whether an applicant is eligible in California to take the NAPLEX and the California MPJE. There will be some modifications to California's application process and forms. These changes are necessary to streamline the process and make it more efficient for the applicant, the board and the schools.

Staff have been working with the NABP on the transition to NAPLEX and the California MPJE. There have been ongoing discussions with the NABP and the Office of Examination Resources on the best approach to implement the computerized component of the California MPJE.

It was also noted that current law (B&P Code sec. 4200.1) requires an applicant who fails to pass the pharmacist licensure examination after four attempts to complete a minimum of 16 semester units of pharmacy coursework before he/she can take the licensure examination for a fifth time. It appears that this law still applies; however clarification has been sought from the board's staff counsel. Preliminary analysis indicates that an applicant who has failed the pharmacist licensure examination 4 times would not be eligible in California to take the NAPLEX and the California MPJE after January 1, 2004. Even if the applicant took and passed NAPLEX in another state, he/she would not be eligible to take California's MPJE until the requirement of 4200.1 is met. **(Attachment B)**

Proposed Regulation Amendments to Implement NAPLEX and California's MPJE

Licensing Committee is recommending to the board that the examination regulations be amended so that they are consistent with the new statutory provisions and the proposed modifications to the application process. **(Attachment C)**

Since the Committee approved this recommendation, staff counsel has advised that the

regulations should include language that clarifies the application process for the NAPLEX and California MPJE. Counsel will be working on this language and if the board approves this action item, then this language will be also be included in the regulatory notice. The following is an overview of the proposed changes:

- 1719 – The primary change in this section is the requirement that an applicant for the examination must complete the required 1,500 hours prior to applying for the examination. This is proposed to streamline the application process
- 1720 – Changes are technical except that a foreign graduate applicant must take the pharmacist licensure examination within one year of application instead of the 5-year period allowed now.
- 1720.1 – Graduates of foreign pharmacy schools who apply to take the California pharmacist licensure examination must be certified by the Foreign Pharmacy Graduate Examination Committee. This certification will streamline the board's application process for foreign graduates. This certification will provide the board with the graduate's transcripts, which the current process doesn't. Also, the certification process entails passing the TSE consistent with the board's current regulatory requirement.
- 1721- These are technical changes. If an applicant engages in dishonest conduct during an examination is not allowed to take the next examination for two years, must surrender his/her intern card and cannot be issued a pharmacy technician permit.
- 1723.1 – Technical changes
- 1724 – NAPLEX and California MPJE scores are communicated as pass/fail. This regulation change is consistent with the guidance provided by the Office of Examination Resources. The board currently establishes its passing score by a criterion-referenced method. The process for establishing the pass score for California's MPJE will not change from current practice.
- 1727 – Technical Changes
- 1728 - Sections (c) and (d) were moved to 1719.

One significant change is that an applicant would be required to complete the 1,500-hour requirement for his/her internship at the time of application for the pharmacist licensure examination. It was discussed that this change might negatively impact those students who will graduate in 2004. While this change would not delay a successful applicants ability to get license, it was suggested that this change not be implemented until after July 1, 2004. It was noted that based on the timeframe for implementing these regulations changes if adopted by the board in January would take a minimum of six months and would not affect the 2004 graduates.

The other change that the Licensing Committee discussed and which Dr. Ferrell explained more thoroughly was the proposed change to section 1724. She stated that the board is not changing how it sets the pass score, it just removing a pass score in the regulation. A licensing examination determines whether a candidate is competent to practice, not whether the candidate performs better or worse than others who take the exam. The written examination measures the knowledge and skills required in practice, and represents a standard of performance that subject matter experts agree is the minimum acceptable level for licensing in the profession. A new version of the examination is implemented at least quarterly to maintain examination security and the integrity of the licensing process.

To establish pass/fail standards for each version of the examination, a criterion-referenced passing score methodology is used. The intent of this methodology is to differentiate between a qualified and unqualified licensure candidate. The passing score is based on minimum competence criterion that is defined in terms of the actual behaviors that qualified pharmacists would perform if they possessed the knowledge necessary to perform job activities.

During a criterion-referenced passing score procedure, a panel of licensed pharmacists also consider other factors that would contribute to minimum acceptable competence such as prerequisite qualifications (e.g., education, training and experience); the difficulty of the issues addressed in each multiple-choice item; and public health and safety issues. By adopting a criterion-referenced passing score, the board applies minimum competence standards to all licensure candidates. Because each examination version varies in difficulty, an important advantage of this methodology allows for the passing score to be lower for a more difficult examination and raised for a less difficult examination, providing safeguards to both the candidate and consumer.

RECOMMENDATION 2

That the Board of Pharmacy approve the proposed regulation change to CCR, title 16, sections 1749, and 1793 – 1793.7 to implement the changes to the pharmacy technician program as a result of SB 361.

Discussion

SB 361 also includes statutory changes to the pharmacy technician program that were recommendations from the board's Pharmacy Manpower Task Force. These changes included the requirement that an applicant for registration as a pharmacy technician has obtained an associate's degree in pharmacy technology. This was changed from an associate arts degree in a field of study directly related to the duties performed by a pharmacy technician. Certification by the Pharmacy Technician Certification Board was added as a qualifier and the experience provision was eliminated. Also, the statute was clarified to allow a graduate from a pharmacy school recognized by the board to be eligible for registration instead of requiring that an applicant be eligible for the board's pharmacist licensure examination.

The regulation amendments are consistent with the provisions of SB 361 and include technical clean up of the language that has not been done since the original adoption in 1990. The changes are:

- 1749 – Moves the technician fees to the same schedule of all other board application and licensing fees. Technical only
- 1793 - Technical changes
- 1793.1 – Moves (g) to 1793.7 and eliminates (h) which is duplicative of existing law
- 1793.2 – Duplicative of existing statute
- 1793.3 – No change. Proposed changes are being considered by the Legislative/Regulatory Committee

- 1793.4 – Eliminates experience as a qualification consistent with SB 361 changes
- 1793.5 – Duplicative of existing statute
- 1793.6 – Amendment removes the specificity of the theoretical and practical aspects of the 240 hours of training
- 1793.7 – Removes the duplicative sections of statute and adds (g) from 1793.1

(Attachment D)

RECOMMENDATION 3

That the Board of Pharmacy approve the proposed statutory revisions to the wholesale licensure requirements.

Discussion

Staff provided the Licensing Committee with proposed changes to the wholesale statutes that are primarily technical in nature with a few exceptions. The intent is to make the law easier to read and understand. However, there are a couple of substantive changes. The first one is the deletion of current subdivision (b) of 4160. This elimination would require all nonresident wholesalers to be licensed in California. Under current law, if an out-of-state wholesaler distributes dangerous drugs through a California licensed wholesaler, the board does not require that the out-of-state wholesaler be licensed with the board. The second substantive change requires an exemptee-in-charge for all nonresident wholesalers. This requirement is consistent with requirements for in-state wholesalers. **(Attachment E)**

RECOMMENDATION 4

That the Board of Pharmacy approve a proposed statutory change that would clarify the licensure requirements for facilities.

Discussion

The Licensing Committee was also asked to consider a legislative proposal to add Business and Professions Code section 4107. This proposal would prohibit any board-licensed facility from being located in a personal residence. Currently this is not a prohibition and it is problematic in that some wholesale facilities are located in the owner's home. Subdivision (b) makes it clear that that board issues a site permit to one premise and it is a separate operation. **(Attachment F)**

ACTION ITEM 5 (Not a Committee Recommendation)

That the Board of Pharmacy determine whether a Limited Liability Company (LLC) can own a pharmacy.

Discussion

Business and Professions Code section 4201 authorizes the board to issue permits for a pharmacy, wholesaler, and veterinary food-animal drug retailer to several types of legal entities, including partnerships, corporations, or other unincorporated associations. This section was amended in 1994 to include Limited Liability Companies (LLCs), and states information which an LLC must include in a permit application. As such, the original interpretation or reading of this section thought that express authority was given for a LLC to operate a pharmacy or other licensed pharmaceutical "business". However, the board's legal counsel researched the issue and concluded that a LLC is ineligible for any license or permit issued by the board because a license for professional services cannot be issued to a LLC. This analysis was provided to board in March 1998.

In October 1998, the board's counsel issued a recommendation that the board may want to consider proposed legislation, which would authorize the board to issue "site" permits to a LLC. He based this recommendation on the fact that current law already authorized the board to issue "site" permits to corporations, which have the same liability shields as a LLC, and that the proposed legislation would not adversely affect consumer protection.

The board accepted the recommendation and tried to sponsor legislation; however, it was met with opposition from the Legislature and an author was never obtained. Therefore, the legislation was never advanced.

In 2000, the Court of Appeals issued a decision that gave guidance as to the interpretation of what constitutes "professional services" in a clear and precise manner. Based on that case, the Legal Office of the Department of Consumer Affairs gave direction as to what licenses are professional versus business, occupation, or vocational, and the department had legal argument that agencies may issue licenses to LLCs by applying the criteria from this case. Essentially the criterion is whether any education or experience is required before an agency will issue a license.

Although no education or experience is required to issue a pharmacy license, the license does require a qualifier. The qualifier is a professional licensee who is legally responsible for the professional acts of the business entity. In the board's case, this is a licensed pharmacist referred to as the pharmacist-in-charge. The pharmacist must be licensed in California and must possess a degree, pass the California licensure examination, and have successfully completed an internship. Staff counsel concluded that a pharmacy license is more of a business and profession hybrid type of license and therefore, the law continued to be unclear.

The board determined that pharmacies are licensed for the primary purpose of "delivering pharmacist's professional services" and therefore, does not meet the criteria of a business license. At its October 2000 meeting, the board took the position that unless legislation is pursued to clarify the law, the board should not license a LLC as a pharmacy.

Because the board had received numerous applications with LLCs in the pharmacy ownership structure, staff requested additional clarification from counsel regarding LLCs owning a pharmacy. The board's counsel concluded that recent developments and refinements of California law indicate that LLCs are persons eligible to apply for licenses to conduct pharmacies. **(Attachment G)**

This conclusion is contrary to the board's current position. Therefore, it is requested that the board consider this new legal analysis and determine if it wants to take action to allow a LLC to own a pharmacy. Because the board has a number of applications pending with a LLC as owner, this issue was brought directly to the board with the permission of the Licensing Committee Chair Clarence Hiura. Otherwise, the issue would have been delayed until the January board meeting. This would have negatively impacted the applicants for a new pharmacy permit.

No Action

Approval Process for Security Printers of Controlled Substance Prescription Documents Pursuant to SB 151 (Burton, Chapter 406, Statutes of 2003)

SB 151 requires the Board of Pharmacy and Department of Justice (DOJ) to approve security printers prior to the production of secure prescription forms for controlled substances. This will require the coordination of security printer approval between the board and the Department of Justice (DOJ). Staff will be working with the DOJ to determine details of how their processes and board processes will interact.

Security printers seeking the board's approval will be required to complete an application form. In addition to the standard questions and criminal background check, the applicant will be required to submit policies and procedures for verifying the identity of the prescriber ordering controlled substance prescription forms, and the policies and procedures for verifying the delivery of controlled substance prescription forms to prescribers.

Once the board approves an application, a copy of the file and a letter from the board will be sent to DOJ for review. If the DOJ approves or fails to take action within 30 days, then the security printer application is approved and a letter is generated to the applicant indicating approval.

Once the final approval is issued, the name and contact information of the approved security printer will be added to the master list maintained on the board's website. If the DOJ rejects the applicant, then DOJ will send a denial letter. The DOJ will also notify the board of the denial and the grounds for the denial. If the Board of Pharmacy denies an application, then the board will send the denial letter. The legislation provides the following as grounds for denying an application: (1) The applicant has been convicted of a crime. (2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another. (3) The applicant committed any act that would constitute a violation of this division. (4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms. (5) The Board of Pharmacy or Department of Justice determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms. (6) The Board of Pharmacy or Department of Justice determines that the applicant has submitted an incomplete application. **(Attachment H)**

Update on the Implementation of the Injectable Sterile Compounding Program for Pharmacies

Supervising Inspector Dennis Ming reported that as of August 28, 2003, the Board of Pharmacy received 174 applications for Sterile Compounding licenses and 126 licenses were issued. Approximately 48 applications are pending because of deficiencies such as incomplete applications, poorly written policies and procedures, and, in the case of out-of-state applications, a lack of a non-resident pharmacy permit.

Dr. Ming stated that the inspectors will continue making these inspections are priority, modify the board's sterile compounding checklist after the regulations are approved, he will meet with inspectors to discuss the compliance of radio-pharmacies and continue to assist licensees in the development of policies and procedures to ensure compliance with the law. **(Attachment I)**

Report from the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBM) Regulation – Recommendation to the Board of Pharmacy that it not take any action to regulate PBMs

At its January 2003 meeting, the board created the Ad Hoc Committee on PBM Regulation. This committee is comprised of the board's public members and is functioning under the auspices of the Licensing Committee. The first meeting was held March 4, 2003, and the second meeting June 4th. Board member Dave Fong facilitated both meetings and both were well attended. The third meeting was held September 11th and was facilitated by Licensing Committee Chair Clarence Hiura. **(Attachment J)**

The purpose of this committee is to determine the need to regulate PBMs in order to protect the public. If the committee determines that PBMs are harming the public and need to be regulated to prevent the harm, then the committee's charge is to determine the regulatory framework.

In order to answer this question, the committee requested that all interested parties, which included the proponents and opponents of PBM regulation, to complete a sunrise questionnaire and submit it by September 1, 2003. This questionnaire is designed to assist proponents of new state boards or new categories of licensed professionals to collect and organize information that is necessary for an objective evaluation. It is intended to determine the merits of governmental regulation to demonstrate the need that licensure and regulation is necessary to protect the public. The questions were to be used as a guide to the committee in making its recommendation regarding regulation.

Dr. Hiura reported that only one completed questionnaire was received. Several PBM organizations participated in the completion of the questionnaire. The committee also received a letter from the Academy of Managed Care Pharmacy (AMCP) and information from the National Community Pharmacists Association (NCPA). NCPA provided a brief overview of PBM legislation introduced this year in other states. All the documents were available on the board's website and at the meeting. **(Attachment K)**

At the last board meeting, the committee requested that staff lay out possible elements of PBM regulation in California. Staff prepared a memorandum that used elements from three principal documents [NCPA Model Law on PBMs, NAIC Draft Model Law on Formulary Development, and a recently enacted Maine statute that imposes disclosure requirements on PBMs]. In addition, the testimony and comment provided at the meetings of the Ad-hoc Committee (committee) on PBM Regulation and during discussions at board meetings were used to form the regulatory elements. **(Attachment L)**

It was explained that the existing model statutes are difficult to apply to California for a number of reasons. First, California is unique in establishing a separate state agency (the Department of Managed Healthcare) for regulating health maintenance organizations (HMOs). Other states generally vest this authority with the state insurance commissioner. Because some limited number of lives are covered through insurance plans regulated by the Department of Insurance, drafting a statute for PBMs, which serve both HMOs and insurers, presents jurisdictional questions. Second, health benefits provided by HMOs are subject to a detailed statutory scheme of regulation (the Knox-Keene Act), which is more extensive than that in other states. Accordingly, any proposal to regulate PBMs in California will require the development of a unique legislative proposal. Such a proposal may well draw conceptual support from these other documents, but the details of how to draft and implement such a proposal will necessarily be specific to California's existing law and the harm that regulation will prevent or ameliorate.

Although the committee continues its efforts to identify the patient harm that would require PBM regulation, there have been a number of issues raised that were used to draft an outline. It was noted that the committee still must answer the threshold question of whether the regulation of PBMs is necessary to protect the public, which should have been addressed by the responses to the sunrise questionnaire.

The possible elements were discussed. The first element is jurisdiction. It was explained that a key aspect of any regulatory proposal is determining which agency (either existing or newly created for the purpose) should assume the responsibility for administering and enforcing the new regulatory scheme. It was noted that there are a number of existing agencies that could regulate PBMs. However, the ultimate determination would be the link between the nature of the regulatory scheme (licensure, disclosure, business practice controls, etc.) and the missions of the relevant agencies. The potential agencies identified were the Department of Managed Health Care, the Department of Insurance, the Department of Consumer Affairs, the Board of Pharmacy, the Department of Health Services, the Medical Board of California and the Managed Risk Medical Insurance Board.

The nature of the regulation was the next element. It was explained that depending on the nature of the harm that regulation seeks to prevent or ameliorate, the particular nature of such regulation may take a number of different forms. For example, the Board of Pharmacy regulates principally through its program of licensure and enforcement actions related to that licensure program. Other avenues include: mandated disclosure (i.e., sunshine laws), direct regulation (inspection and enforcement), creation of a private right of action for violations, or any blend of the above or other approaches.

Another element for regulation could be formulary development. A key aspect of PBM practice is the development, maintenance, and implementation of drug formularies. One potential avenue of regulation would be to specify who may participate in this activity, define the process such activity must follow, and specify the criteria by which formulary decisions must be judged. The NAIC draft model law provides an extensive framework for the regulation of this aspect of PBM practice.

Any regulatory element would need patient protections provisions. Patient protection could take many forms from mandated disclosure of formulary information, reimbursement requirements to establishing rights of appeal or appeal processes. Again, the nature of the protections provided should be narrowly tailored to address problem once it is defined.

It was discussed that much time and attention has been devoted to potential financial conflicts of interest that PBMs may encounter. Establishing a program of financial disclosure to either or both the contracting health plan or the patient has been proposed. It was reported that such a regulatory scheme was recently enacted by Maine. This could be another regulatory aspect that the committee could consider especially as it relates to transparency of the process and oversight by a regulatory agency to ensure that transparency.

Finally, the committee noted that any proposed regulation of PBMs would require the creation of a funding source to support the administration and enforcement of any new requirements. The committee discussed that a funding source sufficient to provide meaningful administration and enforcement of any scheme of regulation it proposes would be necessary.

After considerable discussion, the committee recommended that the board not take any action to regulate PBMs. The committee did state that the board should consider any potential legislation on PBMs that the public may wish to present.

At the conclusion of the meeting, Steve Gray, President-elect of the California Pharmacists Association (CPhA) invited all the participants, PBMs, licensees, employers and health care plan representatives to attend on open forum at CPhA's Annual Meeting in February 2004, to discuss many of the issues that were raised by pharmacists regarding the "noise" in the system so that pharmacists can better assist their patients.

Board member Bill Powers will be unable to attend the October board meeting and will be providing a letter expressing his position on this issue that he requested be read into the record.

Meeting Summary of September 10, 2003 (Attachment M)

Application/Licensing Statistics (Attachment N)

Competency Committee Report (Attachment O)

It was reported to the Licensing Committee that the Pass/Fail letters for the June 2003 examination were mailed to the candidates on Friday, August 15, 2003. However, during the regrading of the essay examinations for this exam, it was discovered that some examination booklets had been incorrectly reassembled for machine scanning and scoring.

Accordingly, staff performed a complete review of the essay examinations for all 1,160 candidates who passed the multiple-choice section of the examination and whose essay booklets were originally graded. This quality control process identified those candidates whose essay booklets were not collated correctly, where one page was incorrectly assembled. Based upon this finding, staff reviewed all scoring decisions for this administration. This review resulted in reconsideration of the passing point for the essay portion of the examination.

On October 10, 2003, the board sent letters to the 1,160 candidates who passed the multi-choice choice section informing them of the incident and notifying those candidates that passed as a result of the re-score.

The pass rate for this examination was 56.5%.

Status Report on Committee Goals for 2003/04 (Attachment P)

Attachment A

California State Board of Pharmacy

California Exam Detailed Content Outline

1. Provide Medication to Patients in Compliance with California Law (29 Percent)

A. Organize and Evaluate Information as Communicated by the Prescriber, Prescriber's Authorized Agent, or Patient/Patient's Representative

1. Assess prescription/medication order for completeness, correctness, authenticity, and legality
2. Assess prescription/medication order for reimbursement eligibility
3. Evaluate the pharmaceutical information needs of the patient/patient's representative

B. Dispense Medications in Compliance with California Law

1. Enter prescription information into patient profile
2. Document preparation of medication in various dosage forms
3. Prepare label(s) for prescription containers
4. Select auxiliary label(s) for container(s)
5. Prior to dispensing, perform the final check of the medication (e.g., correct drug, dose, route, directions)

2. Monitor, Communicate, and Manage Patient Outcomes (31 Percent)

A. Improve Patient Understanding, and Counsel Patient/Patient's Representative in Compliance with California Law

1. Assess the patient's knowledge of the disease and treatment
2. Determine the need for a referral
3. Counsel patient/patient's representative regarding prescription medication therapy
4. Counsel patient/patient's representative regarding herbal/alternative therapies
5. Verify the patient's/patient representative's understanding of the information presented

B. Monitor, Communicate, and Manage Patient Outcomes

1. Communicate results of monitoring to patient/patient's representative, prescriber and/or other health care professionals
2. Adjust patient's drug therapy according to written protocols developed with prescriber(s)

3. Manage Operations in Accordance with California Law (40 Percent)

A. Obtain and Document Pharmaceuticals, Devices and Supplies

1. Maintain a borrow/loan system in compliance with legal requirements

2.	Maintain a record-keeping system of items purchased/received/returned in compliance with legal requirements and professional standards
B.	**Perform Quality Assurance/Improvement to Enhance Patient Safety and Meet Legal Requirements**
1.	Measure, assess and improve the accuracy of medication dispensing by pharmacy staff
2.	Measure, assess and improve patient compliance/adherence with medication regimens
3.	Measure, assess and improve the disease-management outcomes of patient populations
C.	**Manage Operations, Human Resources and Information Systems**
1.	Monitor the practice site and/or service area for compliance with federal, state and local laws, regulations and professional standards
2.	Develop and implement policies and procedures for pharmacy technicians
3.	Supervise the work of pharmacists, pharmacy technicians and/or other pharmacy staff
4.	Ensure the availability of patient-related information (e.g., patient profiles, medication administration records)
D.	**Establish and Manage Medication Use Systems in Accordance with Patient Safety Guidelines and California Law**
1.	Apply therapeutic interchange (e.g., formulary substitution) guidelines
2.	Establish and maintain a system by which adverse drug reactions are documented, analyzed, evaluated and reported
3.	Establish and maintain a system for medication error reporting including root cause analysis

Total: 90 Questions, including 15 nonscored, pretest items

Attachment B

Attachment B:

Will be available when it is approved by Legal Counsel.

Attachment C

Board of Pharmacy
Draft Regulation Changes
Examination
September 24, 2003

Article 3. Licentiates in Pharmacy

§1719. ~~Requirements for Admission to~~ Qualifications for Examination.

(a) Applicants for the ~~pharmacist licensure~~ examination shall have completed all requirements for graduation from a school of pharmacy accredited by the American Council on Pharmaceutical Education or recognized by the Board.
(b) ~~All candidates~~ Applicants for the ~~pharmacist licensure~~ examination shall have completed a minimum of ~~1,000~~ 1,500 hours of intern experience prior to applying for the examination. Applicants for the examination shall submit proof of their intern experience on board-approved affidavits which shall be certified by the pharmacist who supervised the intern while the experience was obtained.[1]
~~(c) All candidates for the pharmacist licensure examination who are graduates of a foreign pharmacy school (any school located outside the United States of America) must demonstrate proficiency in English by achieving a score specified by the board on the Test of Spoken English administered by the Educational Testing Service. For candidates taking the Test of Spoken English after June 30, 1995, a score of at least 50 must be achieved. For candidates taking the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.~~[2]
(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, shall be exempt from subdivision (b).[3]
(d) Applicants shall have all out-of-state licenses verified by the state in which the license is held. Verifications are to be submitted on board-approved affidavits.[4]
(e) For purposes of this division, "examination" means the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California.[5]

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 851, 4005 and 4200 of the Business and Professions Code.

---

[1] Relocation of Section 1728 (c).
[2] Requirement to qualify bases on 4200(a)(2)(B) revised the requirement from passing the equivalency exam offered by FPGEC to FPGEC certification as noted in section 1720.1. Passing the Test of Spoken English (TSE) with a score of 50 or greater is a requirement of being FPGEC certified.
[3] Relocation of Section 1728 (d).
[4] Documentation of license verification specified in regulation.
[5] Definition of examination specified in regulation.

§1720. Application for Examination and ~~Registration~~ Licensure.

(a) An application for ~~the pharmacist licensure~~ examination shall be submitted on the form provided by the board ~~Board~~, and filed with the board ~~Board~~ at its office in Sacramento ~~at least (60) days before the date fixed for examination~~.
(b) The fee required by Section 1749(d) shall be paid for each application for examination. The fee is nonrefundable.
(c) An applicant who fails to pay the fee required by Section 1749(f) within ~~two years~~ one year[6] after being notified ~~by the board~~ of his or her eligibility for a ~~certificate of registration~~ license as a pharmacist shall be deemed to have abandoned the application and must file a new application and meet all of the requirements which are in effect at the time of reapplication~~, including retaking of the examination~~.
(d) ~~Each~~ An applicant for examination whose eligibility is based on the provisions of Business and Professions Code Section 4200(a)(2)(b) and who fails to take the examination within ~~five years~~ one year[7] of the date of filing the application shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

§1720.1. Graduates of Foreign Pharmacy Schools.

~~(a)~~ ~~Each~~ An applicant for ~~admission to the~~ ~~pharmacist licensure~~ examination~~,~~ whose eligibility is based upon the provisions of Business & Professions Code section 4200(a)(2)(B)~~,~~ shall be required to demonstrate ~~that the education obtained at the foreign school is equivalent to that required of domestic graduates by receiving a grade satisfactory to the board on the Foreign Pharmacy Equivalency Examination administered by the National Association of Boards of Pharmacy.~~ to the board's satisfaction certification by the Foreign Pharmacy Graduate Examination Committee.[8]
~~(b) Each applicant for admission to the pharmacist licensure examination whose collegiate study was in a foreign country shall provide transcripts and other reference material sufficient for the board to evaluate an applicant's collegiate equivalency pursuant to Business and Professions Code section 4200(a)(3). If the applicant cannot provide documents sufficient to determine collegiate equivalency, the board may accept the findings of a foreign credentials evaluation service. This service shall be required at the discretion of the board and may include authentication, translation and or evaluation~~

---

[6] Record retention reduced to one year because the combination of adopting NAPLEX and the associated application changes will result in the board holding applications open for significantly less time and still providing the applicant ample time to pay the fees.
[7] Record retention reduced to one year because the combination of adopting NAPLEX and the FPGEC certification process will result in the board holding foreign graduate applications open for significantly less time. The one-year period is ample time for an applicant to complete the process.
[8] Requirement to qualify bases on 4200(a)(2)(B) revised the requirement from passing the equivalency exam offered by FPGEC to FPGEC certification. One of the requirements of FPGEC certification is a passing TSE score of 50 or greater which was previously required in section 1719(c).

~~of such documents as deemed necessary by the board. Any costs for the review shall be paid directly to the evaluation service by the applicant.~~[9]

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

§1721. Dishonest Conduct During Examination.

An applicant for ~~registration~~ examination as a pharmacist who engages in dishonest conduct during the examination shall not have ~~his or her~~ that examination graded, ~~and~~ shall ~~be denied the opportunity to take the examination at its next administration~~ not be approved to take the examination for twenty-four months from the date of the incident, and shall surrender his or her intern card until ~~such time as he or she takes the licensure~~ eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

§1723.1. Confidentiality of Examination Questions.

~~Board of Pharmacy~~ Examination questions are confidential.~~, and any~~ Any applicant for any license~~, permit or exemption certificate~~ issued by the ~~Board~~ board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for ~~the~~ a license~~, permit or exemption certificate for which the applicant applies~~.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4059 and 4200, Business and Professions Code.

§1724. Passing Grade in Examination.

~~The pharmacist licensure examination consists of two sections, multiple-choice and essay, both of which must be passed by achieving a score of 75 or more on each section. A candidate failing the multiple-choice section shall be given a failing grade for the entire examination without regard to the performance on the essay section.~~

In order to pass the examination, an applicant shall be required to obtain a passing score as determined by a criterion-referenced method of establishing the passing point on each part of the examination.[10]

---

[9] FPGEC provides a copy of applicant's transcript when FPGEC verification is requested by the board.

[10] Per Tracy Ferrell of OER, the board should not reference a specific passing score but rather a passing score determined by a criterion-referenced method.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

§1727. Intern Pharmacist.

(a) An intern pharmacist is a person who holds a valid intern card.
(b) An intern card shall be issued for a period of:
(1) One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.
(2) One year to a person who is a graduate of a school of pharmacy recognized by the Board.
(3) One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.
(4) One year to an out-of-state licentiate who is awaiting the administration of the ~~next licensure~~ examination.
(c) Registration as an intern may be ~~renewed~~ issued or extended at the sole discretion of the Board for:
(1) Persons who have not completed experience requirements.
(2) Persons who have completed experience requirements but have not taken or passed the ~~licensure~~ examination. Intern cards shall not be extended or renewed for a person who failed the ~~licensure~~ examination three or more times.
(d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.
(e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

§1728. Intern Experience--Requirements for Licensure.

(a) Minimum Hours: All intern pharmacists must complete 1,500 hours of experience as a prerequisite to licensure.
(1) First Year Maximum: A maximum of 250 of the 1,500 hours may be obtained during the first year of pharmacy education in a program sponsored by a school of pharmacy recognized by the Board.
(2) Preceptor Supervision: A minimum of 900 of the required 1,500 hours must be obtained ~~in a pharmacy~~ under the supervision of a preceptor.
(3) Board Approved Experience: A maximum of 600 of the required 1,500 hours may be granted at the discretion of the Board for other experience which substantially relates to the practice of pharmacy.

(b) Required Areas of Experience: ~~Effective January 1, 1986~~ all applicants for licensure must complete experience in both community pharmacy and institutional pharmacy practice in settings in the following areas:

(1) Receiving and interpreting the prescription;
(2) Patient medication profiles;
(3) Prescription preparation;
(4) Consultation;
(5) Record keeping;
(6) Over the counter products;
(7) Drug information.

~~(c) Proof of Experience: All intern pharmacists are required to submit proof of their experience on Board approved affidavits which shall be certified by the preceptor under whose immediate supervision such experience was obtained.~~ [11]

~~(d) Out-of-State Exemption: One who is licensed as a pharmacist in any state and who has practiced as a pharmacist in that state for at least one year, as certified by the Board of Pharmacy of that state, shall be exempt from the pharmaceutical requirements of this section.~~

Authority cited: Sections 4005 and 4114, Business and Professions Code. Reference: Sections 4114 and 4200, Business and Professions Code.

[11] Sections1728 (c) and (d) have been relocated to section 1719.

Attachment D

Board of Pharmacy
Draft Regulation Changes
Technician Licensing

Amend Section 1749 as follows:

§1749. Fee Schedule.

~~Effective July 1, 1999, the~~ The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with Section 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a permit to conduct a pharmacy is three hundred forty dollars ($340). The fee for the annual renewal of said permit is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).

(b) The fee for the issuance of a temporary permit is one hundred seventy-five dollars ($175).

~~(c) The fee for processing remodeling plans and inspecting the remodeled area is one hundred thirty dollars ($130).~~[1]

(c) The fee for the issuance of a permit for a pharmacy technician shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician permit shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician permit is twenty-five dollars ($25).[2]

(d) The fee for an applicant for examination as a pharmacist is one hundred fifty-five dollars ($155).

(e) The fee for regrading an examination is seventy-five dollars ($75).

(f) The fee for the issuance of an original certificate of registration as a pharmacist is one hundred fifteen dollars ($115).

(g) The fee for the biennial renewal of a pharmacist's license is one hundred fifteen dollars ($115). The penalty fee for failure to renew is fifty-seven dollars and fifty cents ($57.50).

(h) The fee for the issuance or renewal of a wholesaler's permit is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).

(i) The fee for the issuance or renewal of a hypodermic license is ninety dollars ($90). The penalty for failure to renew is forty-five dollars ($45).

(j) The fees for a certificate of exemption under the provisions of sections 4053, 4054 and 4133 of the Business and Professions Code are as follows:

(1) For the application and investigation ~~and examination~~ of the ~~an~~ applicant, the fee is seventy-five dollars ($75).

(2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).

(k) The fee for the issuance or renewal of a license as an out-of-state manufacturer or wholesaler is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).

(l) The fee for registration as an intern pharmacist or extension of the registration is sixty-five dollars ($65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars ($10).

(m) The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars ($30). The fee for the reissuance of any permit, license, or certificate, or renewal thereof,

[1] The board no longer reviews remodeling plans.

[2] This section was moved from 1793.5 to place all fees into a single section.

which must be reissued because of change in the information, other than name change, is sixty dollars ($60).
(n) The fee for registration and annual renewal of providers of continuing education is one hundred dollars ($100). The penalty for failure to renew is fifty dollars ($50).
(o) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
(p) The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty-five dollars ($165).
(q) The fee for the issuance of a clinic permit is three hundred forty dollars ($340). The fee for the annual renewal of said permit is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).
(r) ~~The fee for the issuance of a permit for a medical device retailer is three hundred forty dollars ($340). The fee for the annual renewal of said permit is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).~~[3]
~~(s)~~ The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars ($170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents ($87.50). The penalty for failure to renew is forty-three dollars and seventy-five cents ($43.75).

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4130, 4196, 4200(c), 4400(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (q), (r), (s), (t), (u), (v), (w), 4401 and 4403, Business and Professions Code.

Amend Section 1793 as follows:

§1793. Definitions.

"Pharmacy technician" means an individual who, under the direct supervision and control of a ~~registered~~[4] pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a ~~licensed~~[5] pharmacy, but who does not perform duties restricted to a ~~registered~~ pharmacist under section 1793.1.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Amend Section 1793.1 as follows:

§1793.1. Duties of a ~~Registered~~ Pharmacist.

Only a ~~registered~~ pharmacist, or an intern pharmacist acting under the supervision of a ~~registered~~ pharmacist, may:

[3] The board no longer licenses Medical Device Retailers.
[4] "Registered" is removed because it is redundant. A pharmacist is by definition (B&P 4036) a person licensed by the board.
[5] "Licensed" is removed because it is redundant. A pharmacy is by definition (B&P 4037) a place licensed by the board.

(a) Receive a new prescription order orally from a prescriber or other person authorized by law.
(b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.
(c) Identify, evaluate and interpret a prescription.
(d) Interpret the clinical data in a patient medication record system or patient chart.
(e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.
(f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.
(g) ~~Be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.~~[6]
~~(h) Perform any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform.~~[7]
~~(i)~~ Perform all functions which require professional judgment.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Amend Section 1793.2 as follows:

§1793.2. Duties of a Pharmacy Technician.

~~Pharmacy technicians may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting, and while under the direct supervision and control of, a registered pharmacist.~~[8]
"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:
(a) removing the drug or drugs from stock;
(b) counting, pouring, or mixing pharmaceuticals;
(c) placing the product into a container;
(d) affixing the label or labels to the container;
(e) packaging and repackaging.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Repeal Section 1793.4:

§1793.4. Qualifications for Registration as a Pharmacy Technician.

~~Except for the preparation of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility, no person shall act as a pharmacy technician without first being registered with the board. The board shall issue a certificate of registration to an applicant who has met any of the following requirements:~~

[6] Moved to Section 1793.7.
[7] Eliminated because it is repetitive of existing law.
[8] Eliminated because it is repetitive of existing law (B&P 4115).

~~(a) Has obtained at least an associate of arts degree in one or more fields of study directly related to the duties performed by a pharmacy technician. Directly related fields of study include: health sciences, biological sciences, physical sciences, or natural sciences.~~
~~(b) Has successfully completed a training course specified by the board.~~
~~(c) Is eligible to take the board's pharmacist licensure examination.~~
~~(d) Has at least one year's experience, to include a minimum of 1,500 hours, performing the tasks specified in section 1793.2 while employed or utilized as a pharmacy technician to assist in the preparation of prescriptions for an inpatient of a hospital, for an inmate of a correctional facility, or other experience deemed equivalent by the board.~~
~~(e) A person possesses "experience deemed equivalent by the board" within the meaning of subdivision (d), if he or she has at least 1,500 hours of experience performing the duties specified in section 1793.3 in a pharmacy in the last three years, or has been employed for at least 1,500 hours as a pharmacy technician in another state or by the federal government.~~[9]

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Repeal Section 1793.5:

§1793.5. Application for Registration.

~~The application for registration (Form 17A-5 Rev. 9/94) as a pharmacy technician required by this section is available from the Board of Pharmacy upon request.~~
~~(a) Each application for registration as a pharmacy technician shall include:~~
~~(1) Information sufficient to identify the applicant.~~
~~(2) A description of the applicant's qualifying experience or education, and supporting documentation for that experience or education. Examples of supporting documentation shall include: a certificate of completion issued by the training course provider showing the date of issuance and the number of theoretical and practical hours completed, transcripts, or an experience affidavit (Form 17A-6 or 17A-9 Rev. 9/94) signed by the pharmacist having direct knowledge of the applicant's experience.~~
~~(3) A criminal background check that will require two completed fingerprint cards and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.~~
~~(4) The registration fee shall be fifty dollars ($50) effective July 1, 1995.~~
~~(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.~~
~~(c) The board shall notify the applicant within 30 days whether the application is complete or deficient; and what is needed to correct the deficiency. Once the application is complete, the board will notify the applicant within 60 days of a permit decision.~~
~~(d) Upon review and approval of the application, the board shall issue a certificate of registration as a pharmacy technician for at least one year. Before expiration of the initial certificate of registration, a pharmacy technician must renew the registration certificate with the board. Effective July 1, 1995, the fee is fifty dollars ($50) and the penalty for failure to renew is twenty-five dollars ($25).~~[10]

[9] Eliminated because it is repetitive of existing law (B&P 4202).
[10] Eliminated because the language is outdated and not reflective of SB 361.

Authority cited: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Amend Section 1793.6 as follows:

§1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) ~~1793.4(b)~~[11] is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) Any other course that provides a training period of at least 240 hours of ~~theoretical and practical~~ instruction covering at least the following:~~, provided that at least 120 of these hours are in theoretical instruction in a curriculum that provides~~:[12]

(1) Knowledge and understanding of different pharmacy practice settings.

(2) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Amend Section 1793.7 as follows:

§1793.7. Requirements for Pharmacies Employing Pharmacy Technicians.

~~(a) Any pharmacy which employs a pharmacy technician shall do so in compliance with applicable federal and state laws and regulations governing pharmacy.~~[13]
~~(b)~~

[11] Conforming reference change required by repealing 1793.4.
[12] Changes made to streamline the technician application process.
[13] Eliminated because the language is duplicative of existing law.

(a) Any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

~~(c)~~

(b) Pharmacy technicians must work under the direct supervision of a registered pharmacist and in such a relationship that the supervising pharmacist is ~~on the premises at all times and is~~[14] fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

~~Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, a pharmacy technician may perform the duties, as specified in subdivision 1793.2, only under the immediate, personal supervision and control of a registered pharmacist and within the pharmacist's view.~~[15]

~~(d)~~

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

~~(e)~~

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 ~~12~~ of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.[16]

(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

[14] Changes made reflect the law allowing a pharmacy to operate in the temporary absence of the pharmacist (Section 1714.1) and the existing language is redundant of Section 4115(f).
[15] Duplicative of existing law (B&P 4115).
[16] Moved from 1793.1.

Attachment E

Board of Pharmacy
Draft Revisions to Wholesaler Statutes

Amend Section 4160 of the Business and Professions Code, to read:

4160. (a) No person shall act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
~~(b) No selling or distribution outlet, located in this state, of any out-of-state manufacturer, that has not obtained a license from the board, that sells or distributes only the dangerous drugs or the dangerous devices of that manufacturer, shall sell or distribute any dangerous drug or dangerous device in this state without obtaining a wholesaler's license from the board.~~
(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee.
The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.
(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.
(f) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships drugs of its own manufacture is exempt from this section.

Repeal Section 4161 of the Business and Professions Code:

~~4161. (a) No person shall act as an out-of-state manufacturer or wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. Persons not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer or wholesaler or have an out-of-state dangerous drug or dangerous device distributor's license.~~
~~(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.~~
~~(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer or wholesaler.~~
~~(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.~~

Add Section 4161 to the Business and Professions Code, to read:

4161. (a) Any wholesaler located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
(b) All nonresident wholesalers shall be licensed by the board.
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) A nonresident wholesaler shall disclose to the board the location, names, and titles of:
(1) Its agent for service of process in this state.
(2) Principal corporate officers as specified by the board.
(3) General partners as specified by the board.
(d) A report containing this information shall be made within 30 days of any change of office, corporate officer, or partner.
(e) All nonresident wholesalers shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section.
(f) All nonresident wholesalers shall maintain records of dangerous drugs or dangerous devices sold, traded or transferred to persons in this state so that the records are in a readily retrievable form.
(g) The nonresident wholesaler shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the wholesaler in compliance with the laws of the state in which it is a resident. Applications for a nonresident wholesaler license shall include a license verification from the licensing authority in the applicant's state of residence.
(h) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee.
(i) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. Each nonresident wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge.
(j) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.
(k) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

Repeal Section 4162 of the Business and Professions Code:

~~4162. (a) No person acting as principal or agent for any out-of-state manufacturer, wholesaler, or pharmacy who has not obtained a license from the board, and who sells or distributes dangerous drugs or dangerous devices in this state that are not obtained through a wholesaler who has obtained a license, pursuant to this chapter, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler, pursuant to this chapter, shall conduct the business of selling or distributing dangerous drugs or dangerous devices within this state without registering with the board.~~
~~(b) Registration of persons under this section shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose dangerous drugs or dangerous devices he or she is selling or distributing.~~
~~(c) The board may deny, revoke, or suspend the person's registration for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The board may deny, revoke, or suspend the person's registration if the manufacturer, whose dangerous drugs or dangerous devices he or she is selling or distributing,~~

~~violates any provision of this chapter or any provision of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The registration shall be renewed annually.~~

Amend Section 4163 of the Business and Professions Code, to read:

4163. (a) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.
(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.

Amend Section 4164 of the Business and Professions Code, to read:

4164. All wholesalers licensed by the board ~~and all manufacturers who~~ that distribute controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

Amend Section 4165 of the Business and Professions Code, to read:

4165. ~~(a)~~ Any ~~manufacturer~~ wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.
~~(b) Any manufacturer who fails within a reasonable time, or refuses, to comply with subdivision (a), shall be subject to citation and a fine, an order of abatement, or both, pursuant to Section 125.9 and any regulations adopted by the board, in addition to any other remedy provided by law.~~

Amend Section 4166 of the Business and Professions Code, to read:

4166. (a) Any wholesaler ~~or other distributor~~ that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

Attachment F

Board of Pharmacy
Site Licensing Restriction

Add Section 4107 to the Business and Professions Code, to read:

4107. (a) Effective January 1, 2005, he board may not issue or, effective July 1, 2005, renew a site license, including but not limited to a license to conduct a wholesaler, pharmacy, veterinary food-animal drug retailer, to a facility located in a personal residence.
(b) The board may not issue more than one site license to a single premises except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectible drugs to a pharmacy. For the purposes of this subdivision, "premises" means a location with its own address and a independent means of ingress/egress.

Attachment G

State of California

DEPARTMENT OF CONSUMER AFFAIRS

Telephone: (916) 322-5252
CNET: 8-492-5252
Fax: (916) 323-0971

Memorandum

To: Patricia Harris
Executive Officer
California State Board of Pharmacy

Date: October 2, 2003

From: Dana Winterrowd
Staff Counsel
Legal Affairs Division

Subject: Pharmacy License Applications filed by business associations involving Limited Liability Companies

1

Background and Purpose of Memorandum

This memorandum addresses the issues raised in your memorandum of August 18, 2003, as more fully set forth below.

This office has previously interpreted California law as having the effect of rendering any Limited Liability Company ("LLC") ineligible for any license or permit issued by the California State Board of Pharmacy ("the Board").

However, recent amendments to the Pharmacy Law [Bus. & Prof. Code, § 4000, et seq.] and the Corporations Code, together with recent judicial precedent, indicate that LLCs may now be authorized to conduct pharmacies, as discussed below.

2

Statement of the Issues/Questions Presented

In your August 18 memorandum you pose the following specific questions:

1. Can the Board issue a pharmacy license to a corporation that is owned by an LLC?

2. Can the Board issue a pharmacy license to a corporation that is owned by a partnership, where one or both of these partners is an LLC?

3. Can the Board issue a pharmacy license to a partnership whose members include at least one LLC?

3

Conclusions

1. The Board's issuance of a pharmacy license to a corporation, all of whose shares are owned by an LLC, would not be inconsistent with current California law.

2. The Board's issuance of a pharmacy license to a corporation, all of whose shares are owned by a partnership comprised of partners that include one or more LLCs, would not be inconsistent with current California law.

3. The Board's issuance of a pharmacy license to a partnership comprised of partners that include at least one LLC would not be inconsistent with current California law.

4

Statement of the Facts

Several entities, whose ownership structures include one or more LLCs, have applied to the Board for licenses to conduct pharmacies.

5

Applicable Law and Discussion

Question 1

A licensing board or official has discretion to deny a license if it, he, or she determines that the granting of the license would be contrary to the public welfare. (*Weiss v State Board of Equalization* (1953) 40 Cal.2d 772, 256 P.2d 1.) Such discretion must be exercised within legal bounds, namely, that the discretion not be exercised arbitrarily, capriciously, fraudulently, or without factual basis. (*McDonough v Goodcell* (1939) 13 Cal.2d 741, 91 P.2d 1035.)

In connection with licenses to conduct pharmacies, Business and Professions Code section 4110[1] provides, in relevant part, "No person shall conduct a pharmacy [without] . . . a license from the board."

Section 4035 defines "person" to include a, ". . .firm, association, partnership, corporation, *limited liability company*, state governmental agency, or political subdivision." (emphasis added.)

Parenthetically, section 4111 identifies persons who may not hold a license to conduct a pharmacy. Section 4111 does not include LLCs among those persons forbidden from holding a license to conduct a pharmacy.

Furthermore, section 4201 provides, in relevant part:

> "(a) Each application to conduct a pharmacy . . ., shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.
>
> "(b) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes: . . .
>
> > "(3) If the applicant is a *limited liability company*, each officer, manager, or member.
>
> "(c) In any case where the applicant is a . . . a *limited liability company*, . . ., and where the number of . . . members . . . exceeds five, the application shall so state, and shall

1. All further section references will be to sections of the Business and Professions Code, unless otherwise indicated.

> further state the information required by subdivision (a) as to each of the five . . . members . . .who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to . . .members ....not named in the application, or shall refer the board to an appropriate source of that information. (emphasis added.)

The foregoing provisions of the Pharmacy Law militate against a conclusion that California law forbids the conduct of a pharmacy by an LLC. To the contrary, these provisions indicate that California law specifically contemplates, and is prepared to accommodate, such conduct.

Nevertheless, of some concern are other provisions of law. For example, section 93 of A.B. 469 (Stats. 1994, c.1200) formerly provided,

> "Nothing in this act shall be construed to permit a domestic or foreign limited liability company to render professional services, as defined in subdivision (a) of Section 13401 of the Corporations Code, in this state unless expressly authorized under applicable provisions of the Business and Professions Code or the Chiropractic Act."

However, that provision was supplanted by a provision in Chapter 1000 of the Statutes of 1999, which added section 17375 to the Corporations Code. That section states, in relevant part:

> "Nothing in this title shall be construed to permit a domestic or foreign limited liability company to render professional services, as defined in subdivision (a) of Section 13401...in this state."

Also, section 13401, of the Corporations Code, provides, in relevant part:

> "As used in this part: (a) "Professional services" means any type of *professional services* that may be lawfully rendered only pursuant to a license, certification, or registration authorized by the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act." (emphasis added.)

In the judicial opinion issued in the legal action entitled *Mann v Department of Motor Vehicles* [(1999) 76 Cal.App.4th 312, 90 Cal.Rptr. 277], the California Court of Appeal for the Sixth District pointed out that since at least 1996, California law has recognized a "sharp distinction" between professional licenses and non-professional occupational licenses. The court pointed out that, ordinarily, non-professional occupational licenses can be obtained without meeting any education or skill requirements. (76 Cal.App.4th @ p. 282.) In contrast, in order to obtain a professional license, an applicant must ordinarily satisfy extensive education and training requirements and pass a rigorous state-administered examination. (*Ibid.*)

In this connection, the Pharmacy Law specifically identifies the practice of pharmacy to be a profession. (§ 4050, subd. (a).) The Pharmacy Law also specifies the required qualifications of those "applicants" that are permitted to practice the profession of pharmacy. (See, *Ibid.*, §§ 4051, 4200, 16 Cal. Code Regs. §§ 1719, 1720.) A successful applicant must satisfy extensive education and training requirements and must pass a rigorous state-administered examination. (*Ibid.*)

However, the Pharmacy Law also draws a distinction between the profession of pharmacy and the conduct of a pharmacy. (Compare, *Ibid.*, and §§ 4110, and 4201.)

The conduct of a pharmacy has been recognized as a practice that can be rendered by a "person" rather than by a "pharmacist," an "applicant," or a "professional." The Pharmacy Law imposes no education, training or testing requirements for those "persons" seeking a license to conduct a pharmacy. For these reasons, the provisions of the Pharmacy Law that regulate the issuance of licenses to conduct pharmacies are very likely unrestricted by the Corporations Code provisions discussed above.

Correspondingly, the relatively long-standing policy and practice of the Board has accommodated the granting of pharmacy licenses to non-professional individuals, partnerships and corporations. Such "persons" (§ 4035) have not been required to meet the education, training and testing requirements that are imposed on "applicants" for licenses to practice the profession of pharmacy. The recognition of LLCs as persons authorized to obtain licenses to conduct pharmacies is but the addition of another artificial entity to the ranks of those entities – real and artificial - previously authorized to receive licenses to conduct pharmacies.

In light of the foregoing, the Board's issuance of a license to conduct a pharmacy to a corporation, all of whose shares are owned by an otherwise duly constituted and registered limited liability company, would not be inconsistent with current California law.

Question 2

The analysis provided above in response to Question 1 also indicates that the Board's issuance of a pharmacy license to a corporation, whose shares are owned by a partnership comprised of partners that include one or more LLCs, would not be inconsistent with California law.

Question 3

Similarly, the analysis provided above in response to Question 1 also indicates that the Board's issuance of a pharmacy license to a partnership, that counts an LLC among its partners, would not be inconsistent with California law.

6

Conclusion

Recent developments and refinements of California law indicate that LLCs are persons eligible to apply for licenses to conduct pharmacies. Previously recognized restrictions on the issuance of professional licenses to LLCs appear to have little, if any, application to licenses that authorize the conduct a pharmacy, particularly in light of the Board's long-standing practices. Thus, it would not be inconsistent with California law for the Board to issue a pharmacy license to a "person" [corporation or partnership] that includes an LLC in its ownership structure.

Thank you for giving us the opportunity to review this interesting matter, and if this memorandum fails to respond to your concerns please let us know.

DOREATHEA JOHNSON
Deputy Director
Legal Affairs

By: DANA WINTERROWD
Staff Counsel

Attachment H

State of California Department of Consumer Affairs

Memorandum

To: Patricia Harris
Executive Officer

Date: August 25, 2003

From: Paul Riches

Subject: Security Printer Application Review Process

Senate Bill 151 (copy attached) requires the Board of Pharmacy to approve security printers prior to the production of secure prescription forms for controlled substances. This memo will outline a process for the board to use when granting the required approval. This memo addresses the board's processes only. The bill requires coordination of security printer approval between the board and the Department of Justice (DOJ) and board staff will be working with the DOJ to determine details of how their processes and board processes will interact.

Security printers seeking the board's approval shall complete the application forms and submit them to the board. The application shall contain the following information:

(1) Name of applicant
(2) Address of applicant
(3) Telephone number
(4) Type of Ownership
(5) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms. Soft copies only?
(6) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers. Soft copies only?
(7) The location, name, and title of the applicant's agent for service of process in this state
(8) The location, names and title of all principal corporate officers, if any; or, all managing general partners, if any.
(9) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.
(10) The applicant shall also provide fingerprints as required by the board.

Board of Pharmacy Processing:

(1) Applications will be forwarded to the licensing unit for review.
(2) Licensing unit will notify applicant in writing of deficiencies.
(3) When the application is complete (including fingerprint clearances), the application file is submitted to a supervising inspector for review as follows:

(a) If the supervising inspector approves the application, a copy of the file and a letter from the Board of Pharmacy indicating its approval is sent to the Department of Justice (DOJ) for review.

(b) If the DOJ approves or fails to take action within 30 days, then the security printer application is approved and a letter is generated to the applicant indicating approval.

(b1) The name and contact information of the approved security printer is added to the master list maintained on the board website. Where are complaints filed?

(c) If the DOJ rejects the applicant, then a letter is sent to the applicant by the DOJ indicating denial of their application.

(c1) The DOJ notifies the board of the denial and the grounds for the denial.

(d) If the supervising inspector rejects the application, then a letter is sent to the applicant indicating denial of their application.

The legislation provides the following as grounds for denying the approval:

(1) The applicant has been convicted of a crime.
(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.
(3) The applicant committed any act that would constitute a violation of this division.
(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.
(5) The Board of Pharmacy or Department of Justice determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.
(6) The Board of Pharmacy or Department of Justice determines that the applicant has submitted an incomplete application.

Attachment I

California State Board of Pharmacy
STATE AND CONSUMER SERVICES AGENCY
400 R Street, Suite 4070, Sacramento, CA 95814
DEPARTMENT OF CONSUMER AFFAIRS
Phone (916) 445-5014
GRAY DAVIS, GOVERNOR
Fax (916) 327-6308

August 28, 2003

Patricia Harris
Executive Officer
California State Board of Pharmacy

RE: Status Report: Sterile Compounding Licensing Process

As of August 28, 2003, the Board of Pharmacy has received 174 applications for Sterile Compounding licenses. One hundred and twenty six (73%) of the applications have been issued a Sterile Compounding License. Approximately 48 of the applications (27%) are pending for deficiencies such as incomplete applications, poorly written policies and procedures, and, in the case of out-of-state applications, a lack of a non-resident pharmacy permit.

The following is a breakdown of the applications processed by month:

Month:	Number of Application Processed:
April	9
May	27
June	107
July	26
August	5
Total:	174

At the inception of the program, it was planned the expiration date of the Sterile Compounding License would coincide with the expiration date of the pharmacy license so the licensee would receive only one mailing advising them of the need to renew both licenses. However, during the

first six months of the Sterile Compounding licensing program, there were identified 68 pharmacies who were recently inspected, paid the initial application fee, and issued a Sterile Compounding license whose pharmacy license will expire on or before January 1, 2004. At the approval of the Executive Director, these pharmacies will be sent a letter advising them their Sterile Compounding license expiration date will be extended until their next pharmacy expiration date in 2004 at which time they will be subject to a renewal fee and re-inspection in accordance with Business and Professions Code Section 4127.1 subdivision (c). This will reduce the concerns from the licensees about repaying a fee within a short period and also result in better utilization of inspector resources by eliminating the need to re-inspect pharmacies within a 2-3 month time span.

Pharmacies whose applications are received after August 1st and where it is discovered during the initial inspection process that sterile injectable drugs were compounded and dispensed in the absence of a Sterile Compounding License will be in violation of Business and Professions Code Section 4127.1 subdivision (a).

Future Plans and Action:

1. Continue to monitor and trend the number of applications received versus those approved.
2. Send Sterile Compounding License expiration date extension letters to pharmacies whose pharmacy license expires on or before January 1, 2004.
3. Modify the sterile compounding checklist in the Board of Pharmacy website after the revised California Code of Regulation Section 1751 is finally approved for implementation.
4. Continue to send inspectors on sterile compounding inspections as applications are received.
5. Meet with inspectors to discuss the compliance of radio-pharmacies relative to California Code of Regulation Section 1751 prior to conducting renewal inspections.
6. Continue to assist licensees in the development of policies and procedures to meet compliance with California Code of Regulations Section 1751.
7. Conduct inspections in pharmacies identified as compounding and dispensing sterile injectable drugs who have not applied for a Sterile Compounding License.

Submitted by:

Dennis Ming, Pharm.D.
Supervising Inspector.

Attachment J

TO: MEMBERS OF THE CALIFORNIA BOARD OF PHARMACY

FROM: AD HOC COMMITTEE ON PHARMACY BENEFIT MANAGERS (PBMs), BILL POWERS AND ANDREA ZINDER

DATE: OCTOBER 22, 2003

The Board of Pharmacy established the ad hoc committee composed of public members of the board to determine if PBMs should be regulated by the board or another state agency. This action was taken at the request of several organizations.

The ad hoc committee held three hearings and heard extensive testimony on both sides of the issue. The committee was also presented with a good deal of written material on both sides of the issue. The PBMs who testified believed that they were already regulated, although indirectly, through the Department of Managed Health Care and the Department of Insurance. The ad hoc committee also heard testimony from several groups who felt that PBMs should be regulated because they have become integral players in the health care system.

At the last hearing the ad hoc committee was unable to recommend to the board any action which the board should take relative to licensing or regulating PBMs. However, that is not to say that we do not have serious concerns about some of the activities of PBMs, which may be questionable at best or a conflict of interest at worst. Other states are making efforts to regulate PBMs and while the ad hoc committee did not come up with any recommendations for the board to consider, we believe that other state agencies should consider what their roles might be. We also believe that the Board of Pharmacy should continue to monitor the activities of PBMs to see if there is a role for the board in the future.

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

LICENSING COMMITTEE
AD-HOC Committee on Pharmaceutical Benefit Managers (PBMs) Regulation

Meeting Summary

DATE: September 11, 2003

TIME: 1:00 p.m. – 4:00 p.m.

LOCATION: 400 Street, Suite 4070
Sacramento CA 95814

Ad Hoc Committee Members: Bill Powers, Public Member
Andrea Zinder, Public Member
James Acevedo, Public Member
Caleb Zia, Ex-Officio Member

Board Member and Facilitator: Clarence Hiura, Pharm.D.

Staff Present: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Paul Riches, Chief of Legislative/Regulatory Program

Introductions

Board member Clarence Hiura stated that the purpose of the ad-hoc committee is to gather facts to determine whether PBMs should be regulated. This is the committee's third meeting. Dr. Hiura explained that the goal of this meeting is to determine if the regulation of PBMs is necessary for public protection. If it is, then the committee's charge is to determine the regulatory framework.

Define the Problem – Is Regulation of PBMs Necessary for Public Protection?

In order to answer this question, the committee requested that all interested parties, which included the proponents and opponents of PBM regulation, to complete a sunrise questionnaire and submit it by September 1, 2003. This questionnaire is designed to assist proponents of new state boards or new categories of licensed professionals to collect and organize information that is necessary for an objective evaluation.

While this sunrise questionnaire is typically used for proposed licensure of a new occupational or professional group, it is intended to determine the merits of the governmental regulation to demonstrate the need that licensure and regulation is necessary to protect the public. The questions should guide the committee in making its recommendation regarding regulation.

Dr. Hiura reported that only one completed questionnaire was received. Several PBM organizations participated in the completion of the questionnaire. The committee also received a letter from the Academy of Managed Care Pharmacy (AMCP) and information from the National Community Pharmacists Association (NCPA). NCPA provided a brief overview of PBM legislation introduced this year in other states. All the documents were available on the board's website and at the meeting.

Jerry Shapiro, a community pharmacist-owner of Uptown Pharmacy for 35 years, explained that as a pharmacist, he is an advocate for his patients and one of his primary roles is to help them navigate the health care system. He provided examples of how PBMs have set up roadblocks that impedes the patient's access to their medications. One such roadblock is requiring patients to use mail order especially those patients that require their medications during a narrow period of time. Another example is when a patient changes health care plans. Dr. Shapiro stated that it was his understanding that the law requires a patient to have continual care for prescriptions under a new plan. He felt that the continuity of care should be seamless. It was his experience that it wasn't, and that the patient is required to get a treatment authorization from his/her doctor in order to continue the same drug therapy.

Dr. Shapiro also stated that PBMs have changed the process for obtaining approval for a prescription drug when it is not the drug of choice on the formulary. In these situations, the pharmacist typically calls the doctor and the doctor will change the order to the formulary drug. Even when this was done, the PBM still denied the claim for reimbursement. Dr. Shapiro stated he called the help desk and spoke to a non-pharmacist representative who stated that the doctor was required to get a treatment authorization for the new treatment.

Dr. Shapiro expressed his frustration that he spends an inordinate amount of time when he must call a PBMs' "help desk" to solve problems. He believes that there should be of regulation to require a PBM to perform those functions that they claim they are performing. The PBM needs to be held accountable. PBMs need better staffing on the help desk. PBMs should be required to use pharmacists who understand drug therapy and the latest treatment. The board should require that the pharmacist is accessible to the public. The patient should have immediate and direct access to a pharmacist at a PBM.

It was pointed out that when a patient changes health plans, the law doesn't require that the patient maintain the same medication as the previous plan. It is when a health plan changes its policy; it is then that the health plan is required to continue the same prescription coverage. It was stated that the Board of Pharmacy already regulates mail

order pharmacies. So if a mail order pharmacy is unable to properly service a patient, then the board already has the authority to address the situation. Any restriction that may be on the ordering of a prescription drug is determined by the health plan not the PBM, and patients have an appeal right to that decision. There is an appeal process for the prescriber and the patient when the patient is required to use mail order for a specified treatment.

The pharmacy benefit design is not the decision of the PBM. It is the employer's decision. While regulation may establish certain requirements that affect the design of a pharmacy benefit, it is ultimately the employer's decision whether or not they will pay for that benefit. The PBM is not telling the pharmacist what he or she can dispense as long as it is legally consistent with the physician's prescription. What the PBM is telling the pharmacist is what the third party payor will pay for according to the enrollee's contract. The enrollee always has the option of obtaining a benefit, if the enrollee is willing to pay for it.

Comments were made that the Board of Pharmacy should determine those PBM activities that are the practice of pharmacy. There are some aspects of benefit design and formulary development that should be classified as professional activity and regulated as such to ensure that the profession is being practiced to the patient's benefit.

Possible Elements of Regulation in California

At the last board meeting, the committee requested that staff lay out possible elements of pharmacy benefit manager (PBM) regulation in California. Staff prepared a memorandum that used elements from three principal documents [NCPA Model Law on PBMs, NAIC Draft Model Law on Formulary Development, and a recently enacted Maine statute that imposes disclosure requirements on PBMs]. In addition, the testimony and comment provided at the meetings of the Ad-hoc Committee (committee) on PBM Regulation and during discussions at board meetings were used to form the regulatory elements.

It was explained that the existing model statutes are difficult to apply to California for a number of reasons. First, California is unique in establishing a separate state agency (the Department of Managed Healthcare) for regulating health maintenance organizations (HMOs). Other states generally vest this authority with the state insurance commissioner. Because some limited number of lives are covered through insurance plans regulated by the Department of Insurance, drafting a statute for PBMs, which serve both HMOs and insurers, presents jurisdictional questions. Second, health benefits provided by HMOs are subject to a detailed statutory scheme of regulation (the Knox-Keene Act), which is more extensive than that in other states. Accordingly, any proposal to regulate PBMs in California will require the development of a unique legislative proposal. Such a proposal may well draw conceptual support from these other documents, but the details of how to draft and implement such a proposal will necessarily be specific to California's existing law and the harm that regulation will prevent or ameliorate.

Although the committee continues its efforts to identify the patient harm that would require PBM regulation, there have been a number of issues raised that were used to draft an outline. It was

noted that the committee still must answer the threshold question of whether the regulation of PBMs is necessary to protect the public, which should have been addressed by the responses to the sunrise questionnaire.

The possible elements were discussed. The first element is jurisdiction. It was explained that a key aspect of any regulatory proposal is determining which agency (either existing or newly created for the purpose) should assume the responsibility for administering and enforcing the new regulatory scheme. It was noted that there are a number of existing agencies that could regulate PBMs. However, the ultimate determination would be the link between the nature of the regulatory scheme (licensure, disclosure, business practice controls, etc.) and the missions of the relevant agencies. The potential agencies identified were the Department of Managed Health Care, the Department of Insurance, the Department of Consumer Affairs, the Board of Pharmacy, the Department of Health Services, the Medical Board of California and the Managed Risk Medical Insurance Board.

The nature of the regulation was the next element. It was explained that depending on the nature of the harm that regulation seeks to prevent or ameliorate, the particular nature of such regulation may take a number of different forms. For example, the Board of Pharmacy regulates principally through its program of licensure and enforcement actions related to that licensure program. Other avenues include: mandated disclosure (i.e., sunshine laws), direct regulation (inspection and enforcement), creation of a private right of action for violations, or any blend of the above or other approaches.

Another element for regulation could be formulary development. A key aspect of PBM practice is the development, maintenance, and implementation of drug formularies. One potential avenue of regulation would be to specify who may participate in this activity, define the process such activity must follow, and specify the criteria by which formulary decisions must be judged. The NAIC draft model law provides an extensive framework for the regulation of this aspect of PBM practice.

There was considerable discussion on how formularies are developed; the clinical decisions that are made to place a drug on the formulary and the role rebates play in formulary decisions. Because the United States does not have a single national pharmacy benefit and single national pharmacy staff to negotiate with the drug manufacturers to set controlled prices, a key role for the PBMs is to provide a competitive market to lower drug costs for their customers (the health plans and employers) on behalf of the patient. This is done through a formulary.

Any regulatory element would need patient protections provisions. Patient protection could take many forms from mandated disclosure of formulary information, reimbursement requirements to establishing rights of appeal or appeal processes. Again, the nature of the protections provided should be narrowly tailored to address problem once it is defined.

It was discussed that much time and attention has been devoted to potential financial conflicts of interest that PBMs may encounter. Establishing a program of financial disclosure to either or both the contracting health plan or the patient has been proposed. It was reported that such a

regulatory scheme was recently enacted by Maine. This could be another regulatory aspect that the committee could consider especially as it relates to transparency of the process and oversight by a regulatory agency to ensure that transparency.

Finally, the committee noted that any proposed regulation of PBMs would require the creation of a funding source to support the administration and enforcement of any new requirements. The committee discussed that a funding source sufficient to provide meaningful administration and enforcement of any scheme of regulation it proposes would be necessary.

Recommendations

The committee concluded its review of PBMs and stated that unless there are definitive examples of patient harm that the board can regulate or suggest that another agency for regulation, the committee recommended that the Board of Pharmacy not take any action at this time. The committee also recommended that the Board of Pharmacy consider any potential legislation on PBMs that public may wish to present.

Attachments K and L

Please refer to the Board of Pharmacy Web site on the PBM Meeting of September 11, 2003, for background material on this agenda item.

Attachment M

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE: September 10, 2003

TIME: 9:00 a.m. – 12 noon

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA

BOARD MEMBERS Clarence Hiura, Pharm.D., Chair
Ruth Conroy, Pharm.D.
John Tilley, R.Ph.

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Paul Riches, Legislation Manager
Anne Sodergren, Licensing Program Manager

Call to Order

Committee Chair Clarence Hiura called the meeting to order at 9:00 a.m. He recognized newly appointed board member Ruth Conroy.

Implementation of the Joint Legislative Committee Sunset Review Bill - SB 361 (Pending)

Executive Officer Patricia Harris reported that SB 361 (Figueroa) is the legislative vehicle for the Board of Pharmacy sunset extension and contains statutory recommendations approved by the Joint Legislative Sunset Review Committee. Anticipating that the Governor will sign the legislation, the following is an overview of what the board is doing to implement the NAPLEX and develop a California Multi-State Pharmacy Jurisprudence Examination (CPJE). In addition, it will be necessary for the board to modify its regulations on the examination process and the pharmacy technician program.

Implementation of NAPLEX and California's MPJE

SB 361 will allow an applicant who has passed the NAPLEX and the CPJE on or after January 1, 2004, to be licensed as a pharmacist. Specifically, the bill requires the board when developing the CPJE to include all of the following:

- examination items to demonstrate the candidate's proficiency in patient communication skills
- aspects of contemporary standards of practice for pharmacists in California including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the NAPELX

The bill also requires the board to work with the Office of Examination Resources or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

Tracy Ferrel, Ph.D., Chief, Department of Consumer Affairs, Office of Examination Resources, provided an update on the board's discussions and actions regarding possible transition to the NAPLEX and CPJE if SB 361 is enacted.

She stated that the bulk of the board's activities have been to develop a content outline for the CPJE that encompasses areas identified in California's job analysis that are not covered by the NAPLEX, and that contain items on patient communication and California law which are specifically required by SB 361.

The board's Competency Committee completed the development of the CPJE's content outline during an August meeting, and Dr. Ferrel led the discussion introducing the new content outline. She noted that there was substantial overlap between the content outline for NAPLEX and for California's current pharmacist examination. The CPJE will be comprised of 75 graded items and 15 pretest items (nongraded items that will not be identified as pretest items).

The Competency Committee is now developing questions for the CPJE based on the new content outline. By December 1, there will be a number of questions ready for administration.

It was also reported that board staff have been working with the National Associations of Boards of Pharmacy (NABP) on the transition to NAPLEX and the CPJE. Licensing Program Manager Anne Sodergren was trained on the NAPLEX systems. Also, there will be some modifications to California's application process and forms. These changes are necessary to streamline the process and make it more efficient for the applicant, the board and the schools.

An applicant for licensure in California must also apply concurrently to NABP to take NAPLEX or to have a NAPLEX score transferred to California, and to take the California MPJE. It will be the board's determination whether an applicant is eligible in California to take the NAPLEX and/or the California MPJE. The NAPLEX/MPJE Registration Bulletin can be obtain from

NABP's website.

Ms. Harris also noted that current law (B&P Code sec. 4200.1) requires an applicant who fails to pass the pharmacist licensure examination after four attempts to complete a minimum of 16 semester units of pharmacy coursework before he/she can take the licensure examination for a fifth time. It appears that this law still applies; however clarification has been sought from the board's staff counsel. Therefore, if an applicant has failed the pharmacist licensure examination 4 times, he/she would not be eligible in California to take the NAPLEX and the California MPJE after January 1, 2004. Even if the applicant took and passed NAPLEX in another state, he/she would not be eligible to take California's MPJE until the requirement of 4200.1 is met.

Proposed Regulation Amendments to Implement NAPLEX and CPJE

Ms. Harris explained that with the passage of SB 361, it will be necessary for the board to amend its regulations so that they are consistent with the new statutory provisions and the proposed modifications to the application process. The following is an overview of some of the proposed changes:

- 1719 – The primary change in this section is the requirement that an applicant for the examination must complete the required 1,500 hours prior to applying for the examination. This is proposed to streamline the application process
- 1720 – Changes are technical except that a foreign graduate applicant must take the pharmacist licensure examination within one year of application instead of the 5-year period allowed now.
- 1720.1 – Graduates of foreign pharmacy schools who apply to take the California pharmacist licensure examination must be certified by the Foreign Pharmacy Graduate Examination Committee. This certification will streamline the board's application process for foreign graduates. This certification will provide the board with the graduate's transcripts, which the current process doesn't. Also, the certification process entails passing the TSE consistent with the board's current regulatory requirement.
- 1721- These are technical changes. If an applicant engages in dishonest conduct during an examination is not allowed to take the next examination for two years, must surrender his/her intern card and cannot be issued a pharmacy technician permit.
- 1723.1 – Technical changes
- 1724 – NAPLEX and CPJE scores are communicated as pass/fail. This regulation change is consistent with the guidance provided by the Office of Examination Resources. The board currently establishes its passing score by a criterion-referenced method. The process for establishing the pass score for California's MPJE will not change from current practice.
- 1727 – Technical Changes
- 1728 - Sections (c) and (d) were moved to 1719.

There was discussion regarding the change to require that an applicant has completed the 1,500-hour requirement for his/her internship at the time of application for the pharmacist licensure examination. It was felt that this changed might negatively impact those students who will

graduate in 2004. While this change would not delay a successful applicants ability to get license, it was suggested that this change not be implemented until after July 1, 2004.

Dr. Ferrell explained the proposed change to section 1724. She stated that the board is not changing how it sets the pass score, it just removing a pass score in the regulation. A licensing examination determines whether a candidate is competent to practice, not whether the candidate performs better or worse than others who take the exam. The written examination measures the knowledge and skills required in practice, and represents a standard of performance that subject matter experts agree is the minimum acceptable level for licensing in the profession. A new version of the examination is implemented at least quarterly to maintain examination security and the integrity of the licensing process.

To establish pass/fail standards for each version of the examination, a criterion-referenced passing score methodology is used. The intent of this methodology is to differentiate between a qualified and unqualified licensure candidate. The passing score is based on minimum competence criterion that is defined in terms of the actual behaviors that qualified pharmacists would perform if they possessed the knowledge necessary to perform job activities.

During a criterion-referenced passing score procedure, a panel of licensed pharmacists also consider other factors that would contribute to minimum acceptable competence such as prerequisite qualifications (e.g., education, training and experience); the difficulty of the issues addressed in each multiple-choice item; and public health and safety issues. By adopting a criterion-referenced passing score, the board applies minimum competence standards to all licensure candidates. Because each examination version varies in difficulty, an important advantage of this methodology allows for the passing score to be lower for a more difficult examination and raised for a less difficult examination, providing safeguards to both the candidate and consumer.

The committee recommended that the board approve the proposed regulation changes and set them for a regulation hearing.

Amendments to Implement the Program Modifications for Pharmacy Technicians

Ms. Harris stated that SB 361 included statutory changes to the pharmacy technician program that were recommendations from the board's Pharmacy Manpower Task Force. These changes included the requirement that an applicant for registration as a pharmacy technician has obtained an associate's degree in pharmacy technology. This was changed from an associate arts degree in a field of study directly related to the duties performed by a pharmacy technician. Certification by the Pharmacy Technician Certification Board was added as a qualifier and the experience provision was eliminated. Also, the statute was clarified to allow a graduate from a pharmacy school recognized by the board to be eligible for registration instead of requiring that an applicant be eligible for the board's pharmacist licensure examination.

The regulation amendments are consistent with the provisions of SB 361 and include technical

clean up of the language that has not been done since the original adoption in 1990. The changes are:

- 1749 – Moves the technician fees to the same schedule of all other board application and licensing fees. Technical only
- 1793 - Technical changes
- 1793.1 – Moves (g) to 1793.7 and eliminates (h) which is duplicative of existing law
- 1793.2 – Duplicative of existing statute
- 1793.3 – No change. Proposed changes are being considered by the Legislative/Regulatory Committee
- 1793.4 – Eliminates experience as a qualification consistent with SB 361 changes
- 1793.5 – Duplicative of existing statute
- 1793.6 – Amendment removes the specificity of the theoretical and practical aspects of the 240 hours of training
- 1793.7 – Removes the duplicative sections of statute and adds (g) from 1793.1

The committee recommended that the board approve the proposed regulation changes and set them for a regulation hearing.

Request for Comments to Update the Program Requirements for Intern Pharmacists (CCR, title 16, sections 1727 and 1728)

One of the Licensing Committee's strategic objectives has been to review the requirements for the Intern Program. About 10 years ago, to assist the intern and preceptor in complying with the program requirements, the board developed its Intern/Preceptor Manual, which is available to on the board's website. The Licensing Committee first discussed this issue at its meeting in June. No comments were received in advance of that meeting; however, it was recommended that the internship should include experience obtained under protocol with physicians as allowed by Business and Professions Code section 4052. Licensing Committee Chair Clarence Hiura invited the deans from the California schools of pharmacy to attend this meeting and requested that they bring recommended changes.

There was discussion that the committee update the experience areas for interns and examples were provided such as detecting and resolving drug related problems and performing disease management; however, no specific written revisions were provided. Much of the discussion focused on the practice site where the intern obtains his/her experience. It was suggested that the "residency model" be used to establish minimum site standards that can be enforced. Another suggestion was for the Competency Committee to perform a comprehensive review of the intern program.

Competency Committee Report

It was reported that on August 15, 2003, the board released the results to the June 2003 pharmacist licensure examination. Of the 1,284 candidates, 649 passed for a passing rate of 50.5%. Detailed passing rate information will be available at the October 2003 board meeting. As of the date of this report, 365 pharmacist licenses were issued.

Regrade requests were due to the board office by September 5, 2003. The results will be mailed at the beginning of October.

Proposed Modifications to Statutes for Site Licenses

Proposed Revisions to the Wholesaler Statutes

It was explained that the proposed changes to the wholesale statutes are primarily technical in nature. The intent is to make the law easier to read and understand. However, there are a couple of substantive changes. The first one is the deletion of current subdivision (b) of 4160. This elimination would require all nonresident wholesalers to be licensed in California. Under current law, if an out-of-state wholesaler distributes dangerous drugs through a California licensed wholesaler, the board does not require that the out-of-state wholesaler be licensed with the board. The second substantive change requires an exemptee-in-charge for all nonresident wholesalers. This requirement is consistent with requirements for in-state wholesalers.

The committee recommended that the board approve the proposed statutory changes.

Purchase of Dangerous Drugs and Devices

Ms. Harris reported that these proposed statutory changes are also being discussed at the Enforcement Committee meeting on September 17th. The addition of Business and Professions Code section 4168 is intended to address some public protection issues that the Enforcement Committee has been discussing regarding counterfeit drugs, secondary sourcing and the failure to maintain appropriate records. The language provides for specific citation authority for each violation of this section and the ability for the board to collect unpaid fines from non-licensees through the Franchise Tax Board.

This proposed language was also brought to this committee because current law (Business and Professions Codes section 4163) prohibits a manufacturer or wholesaler from furnishing dangerous drugs or devices to an unauthorized person. Proposed 4168(a) would also prohibit the purchasing of dangerous drugs or devices from an unauthorized person or entity.

Issuance of Site License to a Residence/Issuance of Site License to a Specific Location

The Licensing Committee was also asked to consider a legislative proposal to add Business and Professions Code section 4107. This proposal would prohibit any board-licensed facility from being located in a personal residence. Currently this is not a prohibition and it is problematic in that some wholesale facilities are located in the owner's home. Subdivision (b) makes it clear that that board issues a site permit to one premise and it is a separate operation.

The committee recommended that the board approve the proposed statutory changes.

Exemptee Requirement for Manufacturers

This proposal would move the current requirement from the Business and Professions Code to the Health and Safety Code because Department of Health Services regulates manufacturers.

The committee recommended that the board approve the proposed statutory changes.

Proposed Approval Process for Security Printers of Controlled Substance Prescription Documents Pursuant to SB 151 (Pending)

Paul Riches provided an overview on the implementation SB 151. If enacted, this bill will require the Board of Pharmacy to approve security printers prior to the production of secure prescription forms for controlled substances. The bill requires coordination of security printer approval between the board and the Department of Justice (DOJ) and board staff will be working with the DOJ to determine details of how their processes and board processes will interact.

Mr. Riches explained that security printers seeking the board's approval are required to complete an application form. In addition to the standard questions and criminal background check, the applicant will be required to submit policies and procedures for verifying the identity of the prescriber ordering controlled substance prescription forms, and the policies and procedures for verifying the delivery of controlled substance prescription forms to prescribers.

Once the board approves an application, a copy of the file and a letter from the Board of Pharmacy indicating its approval will be sent to the Department of Justice (DOJ) for review. If the DOJ approves or fails to take action within 30 days, then the security printer application is approved and a letter is generated to the applicant indicating approval.

Once the final approval is issued, the name and contact information of the approved security printer will be added to the master list maintained on the board website. If the DOJ rejects the applicant, then DOJ will send a denial letter. The DOJ will also notify the board of the denial and the grounds for the denial. If the Board of Pharmacy denies an application, then the board will send the denial letter. The legislation provides the following as grounds for denying an application: (1) The applicant has been convicted of a crime. (2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another. (3) The applicant committed any act that would constitute a violation of this division. (4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms. (5) The Board of Pharmacy or Department of Justice determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms. (6) The Board of Pharmacy or Department of Justice determines that the applicant has submitted an incomplete application.

Update on the Implementation of the Injectable Sterile Compounding Program for Pharmacies

Supervising Inspector Dennis Ming reported that as of August 28, 2003, the Board of Pharmacy received 174 applications for Sterile Compounding licenses and 126 licenses have been issued. Approximately 48 applications are pending because of deficiencies such as incomplete applications, poorly written policies and procedures, and, in the case of out-of-state applications, a lack of a non-resident pharmacy permit.

Dr. Ming stated that the inspectors will continue making these inspections are priority, modify the board's sterile compounding checklist after the regulations are modified, meet with inspectors to discuss the compliance of radio-pharmacies and continue to assist licensees in the development of policies and procedures to ensure compliance with the law.

Adjournment

Licensing Committee Chair Clarence Hiura adjourned the meeting at 11:45 a.m. The next meeting is scheduled for December 3rd.

Attachment N

Board of Pharmacy Licensing Statistics - Fiscal Year 2003/04

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	16	22	71										109
Intern pharmacist	89	195	405										689
Pharmacy technician	555	500	793										1848
Foreign educated pharmacists (evaluations)	4	9	98										111
Pharmacy	38	35	51										124
Sterile Compounding	20	10	6										36
Clinics	12	22	14										48
Hospitals	1	2	3										6
Nonresident Pharmacy	9	4	6										19
Licensed Correctional Facility	0	1	0										1
Hypodermic Needle and Syringes	4	9	5										18
Out of State Distributor	5	9	6										20
Wholesalers	8	6	7										21
Veterinary Food-Animal Drug Retailer	1	0	0										1
Exemptees	51	47	61										159
Issued													
Pharmacist	11	421	167										599
Intern pharmacist	79	201	285										565
Pharmacy technician	660	1105	456										2221
Pharmacy	37	51	47										135
Sterile Compounding	95	11	6										112
Clinics	17	12	16										45
Hospitals	1	7	3										11
Nonresident Pharmacy	2	9	10										21
Licensed Correctional Facility	0	1	0										1
Hypodermic Needle and Syringes	2	3	6										11
Out of State Distributor	6	11	5										22
Wholesalers	28	6	9										43
Veterinary Food-Animal Drug Retailer	0	0	0										0
Exemptees	58	45	49										152

Board of Pharmacy Licensing Statistics - Fiscal Year 2003/04

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacist Examination	u/a	u/a	u/a										
Intern pharmacist	u/a	u/a	11										11
Pharmacy technician													
Foreign educated pharmacists (evaluations)	u/a	u/a	18										18
Pharmacy	69	72	74										74
Sterile Compounding	54	53	53										53
Clinics	61	79	77										77
Hospitals	40	10	10										10
Nonresident Pharmacy	54	40	34										34
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	5	14	8										8
Out of State Distributor	46	51	41										41
Wholesalers	42	48	27										27
Veterinary Food-Animal Drug Retailer	1	1	1										1
Exemptees	114	103	104										104
Change of Pharmacist-in-Charge													
Received	170	170	224										564
Processed	114	207	218										539
Pending	139	102	108										108
Change of Exemptee-in-Charge													
Received			3										3
Processed			3										3
Pending			0										0
Change of Permits													
Received	49	57	60										166
Processed	55	10	121										186
Pending	135	182	121										121
Discontinuance of Business													
Received	9	8	16										33
Processed	0	33	11										44
Pending	47	22	27										27

Board of Pharmacy Licensing Statistics - Fiscal Year 2003/04

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacist	2567	1115	1236										4918
Pharmacy technician	1964	971	1216										4151
Pharmacy	970	180	836										1986
Sterile Compounding	0	0	0										0
Clinics	89	49	36										174
Nonresident Pharmacy	25	12	9										46
Hypodermic Needle and Syringes	33	15	20										68
Out of State Distributor	44	12	22										78
Wholesalers	76	24	29										129
Veterinary Food-Animal Drug Retailer	4	6	2										12
Exemptees	252	74	103										429

Attachment O

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

NO ACTION
REPORT ONLY

COMPETENCY COMMITEE REPORT TO THE BOARD MEMBERS FROM THE LICENSING COMMITTEE CLARENCE HIURA, CHAIR OCTOBER 17, 2003

1. Report on the June 2003 Examination

The Pass/Fail letters for the **June 2003** examination were mailed to the candidates on Friday, August 15, 2003.

During regrading of the essay examinations for the June 2003 pharmacist examination, the board discovered that some examination booklets had been incorrectly reassembled for machine scanning and scoring. Accordingly, the board performed a complete review of essay examinations for all 1,160 candidates who passed the multiple-choice section of the examination and whose essay booklets were originally graded. This quality control process identified those candidates whose essay booklets were not collated correctly, where one page was incorrectly assembled. Based upon this finding, the board reviewed all scoring decisions for this administration. This review resulted in reconsideration of the passing point for the essay portion of the examination. On October 10, 2003, the board sent letters to all 1,160 candidates who passed the multi-choice choice informing them of the incident and notifying those candidates that passed as a result of the re-score.

The Pass/Fail statistics for the exam are as follows (percentages for pass/fail ratios noted in parenthesis):

EXAM ATTEMPT	TOTAL	PASSED	FAIL MC	FAIL ESSAY
MC and Essay	1,284	726	124	434
(%)	(100)	(56.5)	(9.7)	(33.8)

For comparison, listed below are the Pass/Fail statistics from our **June 2002** examination.

EXAM ATTEMPT	TOTAL	PASSED	FAIL MC	FAIL ESSAY
MC and Essay	1,156	616	99	441
(%)	(100)	(53.3)	(8.6)	(38.1)

Attached is a June 2003 exam report that describes the performance of candidates and contains detailed demographic information about them. This report was includes the results of the re-scoring but not the regrading.

2. Competency Committee Annual Meeting

The Competency Committee met on August 7 and 8, 2003, for its annual meeting. This meeting focused on development the California Multi-State Pharmacy Jurisprudence Examination (MPJE).

PHARMACIST LICENSURE EXAMINATION –JUNE 2003
PASS/FAIL RATES
CANDIDATES TESTED – 1,284

LOCATION OF GRADUATING SCHOOL:

CALIFORNIA:	
# CANDIDATES	618
% CANDIDATES	48.1%
# PASS	448
% PASS	72.5%
# FAIL	170
% FAIL	27.5%
OTHER U.S.:	
# CANDIDATES	534
% CANDIDATES	41.6%
# PASS	244
% PASS	45.7%
# FAIL	290
% FAIL	54.3%
FOREIGN:	
# CANDIDATES	129
% CANDIDATES	10.1%
# PASS	34
% PASS	26.4%
# FAIL	95
% FAIL	73.6%
UNCLASSIFIED:	
# CANDIDATES	3
% CANDIDATES	0.2%
# PASS	0
% PASS	0%
# FAIL	3
% FAIL	100%

MEAN/STANDARD DEVIATION

		ESSAY	M.C.
CALIFORNIA	MEAN	70.848	235.60
	S.D.	8.1666	20.529
OTHER U.S.	MEAN	65.597	213.96
	S.D.	7.9321	25.635
FOREIGN	MEAN	61.962	209.62
	S.D.	8.5308	25.148

UNCLASSIFIED	MEAN	51.000	199.33
	S.D.	4.2426	17.010

BY GENDER:

FEMALE:

# CANDIDATES	854
% CANDIDATES	66.5%
# PASS	484
% PASS	56.7%
# FAIL	370
% FAIL	43.3%

MALE:

# CANDIDATES	430
% CANDIDATES	33.5%
# PASS	242
% PASS	56.3%
# FAIL	188
% FAIL	43.7%

MEAN/STANDARD DEVIATION

		ESSAY	M.C.
FEMALE	MEAN	68.092	223.51
	S.D.	8.8177	25.604
MALE	MEAN	67.799	224.69
	S.D.	8.4905	26.343

BY DEGREE AWARDED:

B.S.:

# CANDIDATES	234
% CANDIDATES	18.2%
# PASS	71
% PASS	30.3%
# FAIL	163
% FAIL	69.7%

PHARM.D.:

# CANDIDATES	1050
% CANDIDATES	81.8%
# PASS	655

% PASS	62.4%
# FAIL	395
% FAIL	37.6%

DEGREE AWARDED (CONT):

MEAN

ESSAY		M.C.	
B.S.	Pharm.D.	B.S.	Pharm.D
62.476	69.082	209.88	227.03

STANDARD DEVIATION

ESSAY		M.C.	
B.S.	Pharm.D.	B.S.	Pharm.D
8.8173	8.2656	26.065	24.753

BY CALIFORNIA SCHOOL – FIRST TIME CA CANDIDATES:

UCSF:

# CANDIDATES	113
% CANDIDATES	19.3%
# PASS	97
% PASS	85.8%
# FAIL	16
% FAIL	14.2%

UOP:

# CANDIDATES	200
% CANDIDATES	34.3%
# PASS	131
% PASS	65.5%
# FAIL	69
% FAIL	34.5%

USC:

# CANDIDATES	173
% CANDIDATES	29.6%
# PASS	141
% PASS	81.5%
# FAIL	32
% FAIL	18.5%

BY CALIFORNIA SCHOOL – FIRST TIME CA CANDIDATES (CONT):

Western:

# CANDIDATES	98
% CANDIDATES	16.8%
# PASS	64
% PASS	65.3%
# FAIL	34
% FAIL	34.7%

MEAN

ESSAY

UCSF	UOP	USC	Western
74.133	69.247	72.238	70.074

M.C.

UCSF	UOP	USC	Western
244.49	231.59	243.24	226.96

STANDARD DEVIATION

ESSAY

UCSF	UOP	USC	Western
8.2511	7.6572	7.5978	8.3108

M.C.

UCSF	UOP	USC	Western
18.904	18.599	18.221	20.793

U.S. SCHOOLS OF PHARMACY:

SCHOOL	# CANDIDATES	
Auburn	PASS	0
	FAIL	2
Samford (Alabama)	PASS	0
	FAIL	6
University of Arizona	PASS	5
	FAIL	7
University of Arkansas	PASS	0
	FAIL	2
U.C.S.F	PASS	99
	FAIL	18
University of Pacific	PASS	135
	FAIL	72
U.S.C.	PASS	143
	FAIL	38
University of Colorado	PASS	4
	FAIL	9
University of Connecticut	PASS	1
	FAIL	1
Howard University	PASS	0
	FAIL	4
Florida A&M	PASS	0
	FAIL	1
University of Florida	PASS	1
	FAIL	1
Mercer	PASS	2
	FAIL	3
U of Georgia	PASS	2
	FAIL	6
Idaho SU	PASS	7
	FAIL	1

U.S. SCHOOLS OF PHARMACY (CONT):

SCHOOL	# CANDIDATES	
University of Illinois (Chicago)	PASS	5
	FAIL	7
Butler University	PASS	3
	FAIL	0
Purdue University (Indiana)	PASS	1
	FAIL	5
Drake University (Iowa)	PASS	5
	FAIL	8
University of Iowa	PASS	1
	FAIL	1
University of Kansas	PASS	3
	FAIL	1
University of Kentucky	PASS	2
	FAIL	1
NE Louisiana University	PASS	2
	FAIL	3
Xavier	PASS	3
	FAIL	7
University of Maryland	PASS	4
	FAIL	4
Massachusetts College	PASS	21
	FAIL	42
Northeastern University (Massachusetts)	PASS	10
	FAIL	4
Ferris State University (Michigan)	PASS	3
	FAIL	3
University of Michigan	PASS	6
	FAIL	3

Wayne SU	PASS	2
	FAIL	3

U.S. SCHOOLS OF PHARMACY (CONT):

SCHOOL	# CANDIDATES	
University of Minnesota	PASS	3
	FAIL	3
University of Mississippi	PASS	1
	FAIL	0
St. Louis College of Pharmacy	PASS	5
	FAIL	6
University of Missouri-Kansas City School of Pharmacy	PASS	3
	FAIL	3
U of Montana	PASS	1
	FAIL	1
Creighton University (Nebraska)	PASS	16
	FAIL	20
U of Nebraska	PASS	3
	FAIL	3
University of New Mexico	PASS	13
	FAIL	9
Western	PASS	71
	FAIL	42
A&M Schwartz	PASS	11
	FAIL	11
St. John's University (New York)	PASS	2
	FAIL	5
SUNY	PASS	3
	FAIL	2
Union U Albany College of Pharmacy	PASS	3
	FAIL	1
University of North Carolina	PASS	2
	FAIL	3

North Dakota State University	PASS	1
	FAIL	1

U.S. SCHOOLS OF PHARMACY (CONT):

SCHOOL	# CANDIDATES	
Ohio Northern University	PASS	2
	FAIL	2
Ohio State University	PASS	4
	FAIL	1
U of Cincinnati	PASS	1
	FAIL	0
U of Toledo	PASS	3
	FAIL	1
SW Oklahoma State	PASS	1
	FAIL	1
University of Oklahoma	PASS	1
	FAIL	0
Oregon State University	PASS	13
	FAIL	8
Duquesne	PASS	0
	FAIL	3
Philadelphia College of Pharmacy	PASS	6
	FAIL	1
Temple University	PASS	7
	FAIL	20
University of Pittsburgh	PASS	6
	FAIL	2
University of Puerto Rico	PASS	1
	FAIL	1
Medical University of S. Carolina	PASS	0
	FAIL	1
University of Tennessee	PASS	3
	FAIL	3
University of Houston	PASS	4
	FAIL	0

U.S. SCHOOLS OF PHARMACY (CONT):

SCHOOL	# CANDIDATES	
University of Texas	PASS	1
	FAIL	1
University of Utah	PASS	0
	FAIL	2
Medical College of Virginia	PASS	0
	FAIL	2
University of Washington	PASS	6
	FAIL	4
Washington State University	PASS	2
	FAIL	7
University of West Virginia	PASS	0
	FAIL	1
University of Wisconsin at Madison	PASS	9
	FAIL	0
University of Wyoming	PASS	2
	FAIL	2
Campbell University	PASS	0
	FAIL	1
Nova Southeastern	PASS	0
	FAIL	4
Wilkes University	PASS	2
	FAIL	2
Texas Tech	PASS	1
	FAIL	2
Bernard J Dunn	PASS	1
	FAIL	1
Midwestern AZ	PASS	8
	FAIL	14
Unclassified	PASS	0

	FAIL	3

U.S. SCHOOLS OF PHARMACY (CONT):

SCHOOL	# CANDIDATES	
Other/FG	PASS	34
	FAIL	95
TOTAL # OF CANDIDATES	PASS	726
	FAIL	558
	TOTAL	1284

YEAR OF GRADUATION:

1998 OR BEFORE:

# CANDIDATES	202
% CANDIDATES	15.7%
# PASS	55
% PASS	27.2%
# FAIL	147
% FAIL	72.8%

1999 OR AFTER:

# CANDIDATES	1082
% CANDIDATES	84.3%
# PASS	671
% PASS	62.0%
# FAIL	411
% FAIL	38.0%

MEAN

	ESSAY		M.C.
1998 or Before:	62.012	1998 or Before:	210.71
1999 or After:	68.972	1999 or After:	226.36

YEAR OF GRADUATION (CONT):

STANDARD DEVIATION

	ESSAY		M.C.
1998 or Before:	8.8798	1998 or Before:	26.570
1999 or After:	8.2814	1999 or After:	24.969

2001 OR BEFORE:

# CANDIDATES	291
% CANDIDATES	22.7%
# PASS	94
% PASS	32.3%
# FAIL	197
% FAIL	67.7%

2002 OR AFTER:

# CANDIDATES	993
% CANDIDATES	77.3%
# PASS	632
% PASS	63.6%
# FAIL	361
% FAIL	36.4%

MEAN

	ESSAY		M.C.
2001 or Before	62.926	2001 or Before:	212.13
2002 or After:	69.337	2002 or After:	227.34

STANDARD DEVIATION

2001 or Before:	8.5427	2001 or Before:	25.600
2002 or After:	8.2477	2002 or After:	24.906

GRADUATING SCHOOL LOCATION BY COUNTRY:

COUNTRY	# CANDIDATES	
Armenia	PASS	0
	FAIL	2
Argentina	PASS	0
	FAIL	2
Azores	PASS	1
	FAIL	0
Canada	PASS	1
	FAIL	1
China	PASS	0
	FAIL	1
Egypt	PASS	5
	FAIL	7
Ethiopia	PASS	1
	FAIL	1
United Kingdom	PASS	0
	FAIL	1
Israel/W Bank/Gaza Strip	PASS	0
	FAIL	1
India	PASS	8
	FAIL	19
Iran	PASS	0
	FAIL	1
Iraq	PASS	0
	FAIL	3

Italy	PASS	0
	FAIL	1
Japan	PASS	3
	FAIL	0
Jordan	PASS	0
	FAIL	3

GRADUATING SCHOOL LOCATION BY COUNTRY (CONT):

COUNTRY		# CANDIDATES
Korea (N&S)	PASS	3
	FAIL	7
Lebanon	PASS	1
	FAIL	1
Mexico	PASS	0
	FAIL	1
Nigeria/New Guinea	PASS	1
	FAIL	1
Peru	PASS	1
	FAIL	1
Philippines	PASS	2
	FAIL	20
Pakistan	PASS	0
	FAIL	2
Romania	PASS	0
	FAIL	1
Former USSR	PASS	0
	FAIL	1
Syria	PASS	1
	FAIL	2
Thailand	PASS	0
	FAIL	2
Taiwan	PASS	0

	FAIL	1
U.S.A.	PASS	693
	FAIL	464
Vietnam	PASS	0
	FAIL	2

GRADUATING SCHOOL LOCATION BY COUNTRY (CONT):

COUNTRY	# CANDIDATES	
South Africa	PASS	5
	FAIL	9
TOTAL # OF CANDIDATES	PASS	726
	FAIL	558
	TOTAL	1284

PASS RATES BY US/FOREIGN:

	F	P	Rate
U.S.	460	693	54.0%
Foreign	95	33	2.6%
Unclassified	3	0	0%

NUMBER OF TIMES TAKEN:

ONE TIME:

# CANDIDATES	1062
% CANDIDATES	82.2%
# PASS	657
% PASS	61.9%
# FAIL	405
% FAIL	38.1%

TWO TIMES:

# CANDIDATES	110
% CANDIDATES	8.6%
# PASS	33
% PASS	30.0%
# FAIL	77
% FAIL	70.0%

NUMBER OF TIMES TAKEN (CONT):

THREE TIMES:

# CANDIDATES	76
% CANDIDATES	5.9%
# PASS	25
% PASS	32.9%
# FAIL	51
% FAIL	67.1%

FOUR TIMES:

# CANDIDATES	20
% CANDIDATES	1.6%
# PASS	8
% PASS	40.0%
# FAIL	12
% FAIL	60.0%

Requalifiers

# CANDIDATES	14
% CANDIDATES	1.1%
# PASS	2
% PASS	14.3%
# FAIL	12
% FAIL	85.7%

MEAN

	ESSAY			
1	2	3	4	R

69.105	62.148	63.191	61.353	59.250

M.C.

1	2	3	4	R
226.98	206.25	213.32	212.15	205.93

NUMBER OF TIMES TAKEN (CONT):

STANDARD DEVIATION

ESSAY

1	2	3	4	R
8.4129	7.5179	7.9293	9.5259	7.6411

M.C.

1	2	3	4	R
25.469	22.401	22.570	19.837	24.506